

**Amendment and Response**

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Serial No.: 10/822,533

Confirmation No.: 3326

Filed: April 12, 2004

For: BIFIDOBACTERIA AND SIDEROPHORES PRODUCED THEREBY AND METHODS OF USE

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**Remarks**

The Office Action mailed March 28, 2006 has been received and reviewed. Reconsideration and withdrawal of the rejections are respectfully requested.

**Specification**

The present application has been amended at page 1, line 8, to update the status of the parent application.

**Election/Restrictions**

Applicants note with appreciation the decision to remove the restriction and examine all pending claims.

**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 41-58 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the language "when cultured in a medium comprising at least about 0.3 mM 2,2'-dipyridyl, secretes a siderophore, and wherein the siderophore inhibits growth of *Lactococcus lactis*" is asserted to render the claims vague and indefinite. The rejection is respectfully traversed.

A person of ordinary skill would recognize that this language defines the metes and bounds of the claims. In fact, the Examiner correctly notes that the composition does not require the isolated bacterium to be cultured in the medium. As also correctly noted by the Examiner, the language "when cultured" indicates that the Bifidobacterium does not necessarily require these conditions for its isolation. Thus, the language of the claim is clear, and the skilled person would recognize that the language cited by the Examiner defines the metes and bounds of the claims.

Even if the metes and bounds of the claims were not readily recognizable to one of skill in the art, the meaning of the claim recitation is clear in view of the disclosure. For instance,

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Example 1 teaches how to isolate *Bifidobacterium* strains, and the isolation does not require culture in a medium comprising at least about 0.3 mM 2,2'-dipyridyl. Further, the specification states that various iron chelators can be used at various concentrations (page 10, line 15 through page 11, line 2). Thus, the skilled person would readily recognize that the composition as claimed would not require culture in the conditions disclosed in claims 41 and 48.

For at least these reasons reconsideration and withdrawal of the present rejection is respectfully requested.

**The 35 U.S.C. §102 Rejection**

The Examiner rejected claims 41-58 under 35 U.S.C. §102(e) as being anticipated by Masuyama et al. (U.S. Patent No. 6,284,243). This rejection is respectfully traversed.

Masuyama et al. disclose a physiologically functional food containing a lactic acid bacterium fermented milk, a lactic acid bacterium and yeast co-fermented milk (Masuyama et al., col. 2, lines 45-49). The lactic acid bacterium fermented milk or a lactic acid bacterium and yeast co-fermented milk can be obtained by fermenting milk or a milk component with a lactic acid bacterium or co-fermenting it with a lactic acid bacterium and a yeast (Masuyama et al., col. 2, lines 49-54). Examples of lactic acid bacteria that can be used include those which belong to the genera *Bifidobacterium* (Masuyama et al., col. 2, lines 55-61).

In characterizing the claims, the Examiner asserts that "[t]he composition comprises an iron chelator" (Office Action at page 4, second full paragraph). This is not true. The composition of independent claim 41 comprises an isolated *Bifidobacterium* and either a food or a beverage. Independent claim 48 is a method for administering a live microbial feed supplement, comprising providing an isolated *Bifidobacterium*. The isolated *Bifidobacterium* secretes a siderophore when cultured in a medium comprising at least about 0.3 mM 2,2'-dipyridyl and the siderophore inhibits growth of *Lactococcus lactis*; however the claimed composition and method does not comprise an iron chelator.

The Examiner asserts the composition of Masuyama et al. "comprises an iron chelator, note column 3, lines 66-67 wherein vitamin and minerals as well as protein are disclosed to be

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present. Minerals such as cobalt and magnesium function as iron chelators" (Office Action at page 4, third full paragraph). The Applicant disagrees with the assertion that the compositions of Masuyama et al. comprise an iron chelator. To begin with, the Applicant was unable to identify any passage in Matsuyama et al. teaching an iron chelator. Furthermore, the compositions of Masuyama et al. are produced by fermentation with a lactic acid bacterium or a lactic acid bacterium and a yeast (Masuyama et al., col. 2, lines 49-54, and the first paragraphs of Examples 1 and 3 of Masuyama et al.). Fermentation by a lactic acid bacterium or a lactic acid bacterium and a yeast will lower the pH of the fermented composition. Iron is soluble at lower pH, and is therefore non-limiting in the fermented milk taught by Matsuyama et al. (see the present specification at page 11, lines 3-11). Acid conditions will remove iron from chelators, so the presence or absence of a chelator in the composition taught by Matsuyama et al., would not render the iron status limiting for microbial growth.

The Applicant also disagrees with the assertion that minerals such as cobalt and magnesium function as iron chelators. "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." M.P.E.P. §2144.03(A). The Office has not provided specific factual findings based on sound technical and scientific reasoning to support the assertion that minerals such as cobalt and magnesium function as iron chelators. The Office is requested to provide documentary evidence that supports the assertion, or an affidavit or declaration setting forth specific factual statements and explanation to support the finding. M.P.E.P. §2144.03(C).

According to MPEP § 2131 a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." The present invention is directed to a "composition comprising an isolated *Bifidobacterium* . . . wherein the isolated *Bifidobacterium*, when cultured in a medium comprising at least about 0.3 mM 2,2'-dipyridyl, secretes a siderophore, and wherein the siderophore inhibits growth of *Lactococcus lactis*" (independent claim 41), and a method for administering a live microbial feed supplement comprising "providing an isolated

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*Bifidobacterium*, wherein the isolated *Bifidobacterium*, when cultured in a medium comprising at least about 0.3 mM 2,2'-dipyridyl, secretes a siderophore, and wherein the siderophore inhibits growth of *Lactococcus lactis*" (independent claim 48).

Masuyama et al. teach that a *Bifidobacterium* can be used in the compositions described therein. This description of *Bifidobacterium* is generic; no specific strain is described. Moreover, Masuyama et al. do not explicitly state that the *Bifidobacterium*, when cultured in a medium comprising at least about 0.3 mM 2,2'-dipyridyl, secrete a siderophore, and wherein the siderophore inhibits growth of *Lactococcus lactis*. Masuyama et al. does not set forth each and every element as set forth in the claims, thus Masuyama et al. does not anticipate the claims.

To the extent the doctrine of inherency is used to support the contention that Masuyama et al. teach the *Bifidobacterium* recited in independent claims 41 and 48, it is Applicant's position that the doctrine of inherency cannot be used to supplement the deficiencies of Masuyama et al. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art" (emphasis in original). M.P.E.P §2112. No basis in fact and no technical reasoning supporting an assertion of inherency is provided in the Action; only conclusory statements are provided. Thus, the Office has not made the initial showing required to rely upon the theory of inherency.

Further, the Examiner is requested to note that "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic" (emphasis in original). M.P.E.P §2112. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " M.P.E.P §2112.

The Examiner is respectfully requested to consider the following as evidence that the allegedly inherent characteristic does not necessarily flow from the teachings of the cited art.

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The present application discloses that prior to the present invention, Bezkorovainy (In: Biochemistry and Physiology of Bifidobacteria, Bezkorovainy et al., (eds.), CRC Press, pp. 147-176 (1989)) investigated the ability of bifidobacteria to secrete a siderophore, and it was concluded that bifidobacteria did not (specification, page 5, lines 3-6, and lines 19-22). In particular, the Examiner is requested to note that Bezkorovainy teaches that "[i]ron transport in bifidobacteria does not involve the participation of siderophores" (page 174 of Bezkorovainy). Thus, a skilled person would not recognize that the bifidobacteria of Masuyama et al. would necessarily secrete a siderophore. Secondly, the present application discloses in Examples 1 and 2 the isolation of bifidobacteria and detection of siderophore production by the bifidobacteria. Of the 29 strains isolated, 8 were found to produce a diffusible compound that was preferentially produced during incubation in low iron conditions and inhibited the growth of indicator strains. This observation that 8 of 29 strains produced the siderophore indicates that the ability to produce a siderophore is not necessarily present in all bifidobacteria.

Even if a *Bifidobacterium* taught by Matsuyama et al. did produce a siderophore under the conditions recited in claims 41 and 48, such a property would be inherent only if there is at least a reasonable likelihood that one of skill in the art could have discovered or recognized that property without specific guidance. The subject matter relied upon must be disclosed in a manner to place it in possession of the public. See, e.g., Akzo N.V. v. United States Int'l Trade Comm'n., 1 USPAd 1241 (Fed. Cir 1986).

For at least these reasons, reconsideration and withdrawal of the rejection of claims 41-58 under 35 U.S.C. §102(e) as being anticipated by Masuyama et al. (U.S. Patent No. 6,284,243) is respectfully requested.

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Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 28<sup>th</sup> day of June 2006, at 12:30pm (Central Time).

By: Sue DombroskeName: Sue Dombroske